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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,752	06/18/2001	John Charles Kath	PC 10760A	1737

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06/12/2003

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/12/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/883,752

Applicant(s)

KATH ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-16, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 5, 7-11, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,284,764.

The reasons were given previously; the traverse is unpersuasive. Applicants have placed the claim 4 limitations into claim 1, so that now claim 1 (and claim 21) have the same status as claim 4 and are obvious.

Applicants state, "The Examiner merely recites bits and pieces from the '764 patent..." This is incorrect. The examiner has pointed specifically to examples 75, 76, 125 and 141. For example, the species of example 75 differs from the claims solely in that it has the CH₂ between the oxygen atom and the pyridine. That is, the claim has py- attached to the oxygen, the claim has py-CH₂-. The entire rest of the molecule - the oxygen, the phenylene, the amino, the quinazoline, the alkynylene linker, the tetrahydropyran, and its OH substituent -- is the same. That precise equivalency is taught at column 59, line 59, with the term Heterocycle-(CR¹R²)_q-O-. Note that q can be 0-5 as seen at lines 62-63. Thus, q=1 corresponds to the species of the reference, q=0 corresponds to the species of the amended claims. The reference states that the two are alternatively useable, and thus the q=0 is just an obvious variation of the q=1 species of

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the prior art. Thus, while Applicants state that the examiner, "has provided no rhyme or reason", the examiner has pointed to the fact that the reference teaches the exact difference between the prior art compounds and the claimed compounds.

Applicants at page 7, line 2 next ask, "where ... is some teaching..." It is as indicated, in the definition of q, which corresponds to the variable t in this application.

Applicants next argue that the examiner "relies on a significant number of assumptions and unsupported intellectual modifications." A similar argument is made on page 9 as well. This is not correct. The examiner has not in fact modified the reference at all. Applicants claims fall within the genus of the reference itself; the reference does not have to be modified in any way. The examiner has simply pointed to what the reference teaches, both by way of 4 specific examples and by the definition of q. Applicants give as an "unsupported modification" "the selection of R8 ... as an aryl and more particularly as a 'phenyl'". This is not a modification. It is what the reference actually teaches. The four examples that the examiner points to all have the phenyl, as do of course many other species.

Applicants next point in the paragraph bridging pages 7-8 to the fact that there are many other choices for R10 other than the ones in the 4 examples that the examiner relies on. This is true but has no bearing on patentability. Nearly all references have aspects to them which do not render the claims obvious. The presence of that material does not undermine what the reference teaches.

Next, applicants argue that the examiner should focus on "the obviousness of the claimed invention as a whole". This is what the examiner has done. Taken as a whole,

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the entire rest of the molecule of these four species falls within what claim 1 covers.

There is only one tiny difference, that of the methylene group.

Next, applicants state that the examiner has relied on "hindsight reconstruction".

That is not what is occurring here. Applicants point to *In re Jones*, 21 USPQ2d 1941, 1943. But that had the opposite fact pattern as here. First, the claim there was drawn to a single species, not a broad claim as here. Second, the two actual species of the reference were examined and found not to be "closely related in structure". The first Richter species was a secondary amine, and was not an ether, whereas the claim was drawn to a primary amine which was an ether. The second was a cyclic amine, whereas the claimed compound was a non-cyclic, a substantial difference. By contrast, the four species that the examiner points to are of extremely close structure. Applicants have also cited *Ashland Oil v. Delta Resins*, 227 USPQ 657 and *In re Rouffet* 47 USPQ2d 1453, but both of those cases turned on the question of the obviousness of combining references, not a issue here.

Next, applicants focus on claim 11, which has $k = 1$, while the 4 indicated species have $k=0$. This presents the same issue, as the reference at column 2, lines 62-63 teaches that $t = 0-5$ (t is the variable that corresponds to k in claim 11).

Applicants next turn to the question of claim 5. Claim 5 requires that the pyridine ring be bound at the 3-position (second current choice for R3 as seen in claim 1) whereas the four prior art compounds are the 2-pyridyl. Applicants argue, "No where does the examiner provide the rationale or logic to make the present invention." To the contrary, the examiner pointed out that the teaching of where the substituent appears is not limited to any position. In fact, the reference at column 11, lines 53-55 makes it clear

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that any position is suitable, giving as an example a pyrrole bonded at the 1 position of the 3-position. With regard to the law, the examiner cited 17 cases. Every one of these dealt with the obviousness of position isomers, where the position isomer was deemed obvious without any secondary teaching. By contrast, applicants cite cases, not one of which has to do with this issue. For example, *In re Stemniski*, 170 USPQ 343 deals with the issue of whether a 35USC 103 rejection can be made over a reference with no utility taught, certainly note the case here, where the utility of the reference is the same. Indeed, one case cited by applicants *In re Jones*, 21 USPQ2d 1941, actually supports the examiner's position. While the case does not deal with position isomerism, there is dicta which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to *prima facie* obviousness"; one of those listed is "structural isomers". Position isomers are a basic form of close "structural isomers." See in this regard MPEP 2144.09, second paragraph, which states, "Compounds which are position isomers ... are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties."

Finally, applicants argue that this is an "obvious to try" situation. It is not. *In re O'Farrell*, 7 USPQ2d 1673 discussed the two types of obvious to try situations. First, "...to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many choices is likely to be successful." Obviously, that is not the case here, since the species indicated are already virtually identical to what the claims require. The second circumstance is "to explore a new technology or general approach that seems like a promising field of

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experimentation where the prior art gave only general guidance.” This is clearly not the case either. The prior art does not give “only general guidance”; it specifically teaches very close species, and the modification which needs to be made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 7-11, and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,284,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons given above. The same issues arise. There is no patentable distinctness from the four species of the patent for exactly the reasons given above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 4-16, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to solvates. But the hundreds of examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

The traverse is unpersuasive. It does not address the essential thrust of the examiner’s argument, which is that all attempts to prepare solvates failed. Applicants state correctly that preparation of solvates is well known, and that it “is not uncommon to have solvents such as methylene chloride ... forming solvates with organic compounds prepared in these solvents.” Agreed, but from the evidence of record, these particular compounds simply don’t form solvates. That failure is the evidence that the examiner relies upon, exactly as the failure in *Morton* was relied upon, as evidence of

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non-enablement. The compounds prepared in *Morton* failed to have the required property, just as the compounds prepared here failed to have the required property.

Claim Objections

Claims 4 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

A. Claim 4 is now identical to claim 1, and thus fails to further limit.

B. The species of claim 6 at page 79, lines 10-28 are not provided for in claim 1, as pyrazines are not in the amended R³ choices.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.

A handwritten signature in black ink, appearing to read 'Mark L. Berch', written in a cursive style.

Mark L. Berch
Primary Examiner
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June 4, 2003